

US-PAT-NO: 6527919

DOCUMENT-IDENTIFIER: US 6527919 B1

TITLE: Thin film stent

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Brief Summary Text - BSTX (9):

In the far-afield arts of micro-machines and microactuators, the fabrication of shape memory switches of microscopic proportions has been proposed. The fabrication technique is called sputter deposition. The resultant material is referred to as a thin film. The sputter-deposited films have been experimentally used in micro-valves and micro-grippers.

Thin film sputtering processes are used in the manufacture of microchips to lay down very small and very thin circuit lines on circuit substrates such as silicon chips. Thin film processes are used to coat plastic articles with decorative chrome finishes.

In general, thin film sputter techniques use high power electromagnetic fields to create energetic particles or photons (plasma ions, ion beams, electron beam, laser beam) directed toward a target plate of the coating material to

dislodge single atoms or molecules of the coating material onto a substrate.

The dislodged atoms or molecules condense on the substrate and adhere very strongly to the substrate. The sputter process is usually performed at very high temperature of one hundred to several hundred degrees centigrade, and performed within an atmosphere of very high vacuum and/or an atmosphere of an inert gas. Sputter techniques are part of a broader field of processes

referred to as physical vapor deposition or PVD techniques.

The PVD processes are part of the broader field of thin film deposition, which also includes chemical vapor deposition, and electroplating. The key to all these processes is the placement of the substrate (the article to be coated) in an atmosphere or cloud of film molecules.

Detailed Description Text - DETX (9):

Other sputtering techniques are variations on this basic technique. In ion beam sputtering, the ion beam is created using a ion beam gun. The ion beam gun directs a stream of ions at the target material to dislodge target atoms. The substrate is place in the chamber near the target to collect the dislodged atoms. In this system, the target is not electrified. The process of vacuum evaporation uses the combination of heat and very low pressure to evaporate or sublime the target in the vicinity of the substrate, so that the evaporated target molecules condense on the substrate. The heat may be provided thermally, through resistive heating of the target, or by irradiating the target with laser energy from a laser, an electron beam emitted from an electron beam emitter. Vacuum evaporation deposition is a line of sight deposition technique. For some stent compositions, chemical vapor deposition may be used. Chemical vapor deposition permits reaction of chamber atmosphere components with each other or with ejected target material to form the deposited compound.

Detailed Description Text - DETX (16):

The perforation pattern on the stent sheet may be created with several methods. The perforations may be photochemically etched into the nitinol film

after formation of the film into stent sheet, or the release layer may be etched and undercut with subsequent sputter deposition onto the remaining top surface of the release layer.

Detailed Description Text - DETX (19):

The process is illustrated in FIG. 6. At step A, the substrate 36, removable oxide layer 50 are coated with a waste layer 52. The waste layer may be comprised of a photoresist compound or other readily removable material. If made of a photoresist, the waste layer is imaged (exposed and developed) with a reverse image of the desired stent. At step B, the waste layer has numerous perforations 53 which correspond to the actual structure of the stent, and numerous strips and coated areas 54 which correspond to the perforations of the stent. The side walls 55 of the coated areas are undercut (to this end, the waste layer may be comprised of two layers, a top layer which is imaged and developed, followed by non-directional etching or wet etching of the underlying layer). The process creates a reverse slope photoresist side-wall profile. In step C, the stent material is sputtered with a line of sight deposition technique which avoids coating the side walls 55 (in contrast to step coverage or conformal coverage). The result is a layer of thin film of nitinol 56 on the substrate and a thin film of nitinol 57 on the waste layer. The film 56 on the substrate is the stent, formed as desired with perforations, struts, staves, and border areas as dictated by the reverse image in the photoresist applied in step B. In step D, the waste material is dissolved and removed, along with waste film 57 sputter on top of the waste material. In step E, the silicon oxide layer 50 is dissolved away to remove the fully formed stent from

the substrate.

Detailed Description Text - DETX (21):

The lift off process places the waste nitinol material over the waste layer 52, and sputters the desired film onto the substrate. The process may be reversed as illustrated in FIG. 7 as follows: At step A, the substrate 36 and removable oxide layer 50 are coated with a waste layer 52. The waste layer may be comprised of a photoresist compound or other readily removable material. If made of a photoresist, the waste layer is imaged (exposed and developed) with positive (rather than a reverse) image of the desired stent. At step B, the waste layer has numerous perforations 58 which correspond to the actual perforations of the stent, and numerous strips and coated areas 59 which correspond to the actual structural elements of the stent. In step C, the stent material is sputtered with a line of sight deposition technique which avoids coating the side walls 55. The result is a layer of thin film of nitinol 60 on the substrate and a thin film of nitinol 61 on the waste layer. The film 60 on the substrate is the wasted thin film stent, while the film 61 on the waste layer is the stent, formed as desired with perforations, struts, staves, and border areas as dictated by the positive image in the photoresist applied in step B. In step D, the photoresist is dissolved away in a bath of acetone or other solvent. In this process, the material "lifted off" is the desired stent. In either process of lift off or reverse lift off, the photoresist may be a positive (exposed areas become soluble) or negative photoresist (exposed areas become insoluble) which may be exposed with a positive or reverse image of the desired stent. Thus, where the waste

perforations are lifted off (leaving a positive on the substrate), and the waste material is a positive photoresist, the photoresist is exposed in areas corresponding to the stent structure (rather than the perforations) and the photoresist is developed to remove the exposed areas. Where the wasted stent material is lifted off and the waste material is a negative photoresist, the photoresist is exposed in areas corresponding to the stent perforations (rather than the structure) and the photoresist is developed to remove the unexposed areas. Where the waste perforations are deposited on the substrate and the actual stent is deposited on the waste material, and the waste material is a positive photoresist, the photoresist is exposed in areas of perforation and the photoresist is developed to removed exposed areas. Where the waste perforations are deposited on the substrate and the actual stent is deposited on the waste material, and the waste material is a negative photoresist, then the photoresist is exposed in areas of stent structure and the photoresist is developed to remove unexposed areas.

Detailed Description Text - DETX (22):

The strength and resilience of the stent may be improved with hot isostatic processing (HIP or hipping) of the stent to remove voids in the sputtered stent and increase the density of the stent. In this process, after the sputtered stent has been released from the substrate and etched to form the perforation patterns, it is placed in a HIP chamber for exposure to a high pressure, high temperature atmosphere of inert gas (argon) to eliminate any voids in the thin film. Temperatures up to 2000.degree. C. and pressures up to 650 MPa (94,000 psi) may be applied in the process, and the pressure and temperature may be

applied for variable time periods of minutes to hours, depending on how long it takes for the voids in the stent to fill. After hipping, the thin film can be additionally strengthened by cold working, for example by pack rolling the thin film in one or more passes through a thin film roller. (Since hipping generally increases fatigue life of the hipped article, it may beneficially be used with all stents, implanted prostheses and other medical devices subject to repetitive stress. It may also be beneficially applied to sputtered nitinol actuators generally, such as the micro-valves and micro-grippers mentioned in the background.)